



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-00-13

December 1, 1999

Roberto Medio, President
RMJ Sandwich Corporation
2114 West 62nd Street
Hialeah, Florida 33016

Dear Mr. Medio:

We inspected your sandwich manufacturing plant on August 18, 1999 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your ready-to-eat tuna salad sandwiches to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find the Act and these regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for your ready-to-eat tuna salad sandwiches to control the potential food safety hazard of pathogens.

You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm is not monitoring plant water safety, cleanliness of food contact surfaces, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection from adulterants, proper labeling, storage and use of toxic compounds, control of employee health conditions, and exclusion of pests with sufficient frequency to ensure control.

You must have sanitation control records that document the monitoring and correction during processing of the sanitation conditions listed above, in order to comply with 21 CFR 123.11(c). However, sanitation control records are not being maintained by your firm.

Roberto Medio
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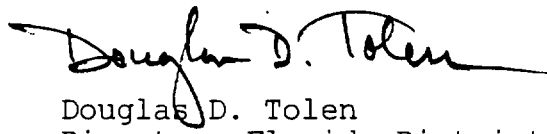
These same deviations were previously brought to your attention in our letter of April 20, 1999. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your ready-to-eat tuna salad sandwiches and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plan for ready-to-eat tuna salad sandwiches, sanitation control records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP regulations and the GMP regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

A handwritten signature in black ink, reading "Douglas D. Tolen". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Douglas D. Tolen
Director, Florida District